

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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DIAPULSE CORPORATION OF AMERICA,

Plaintiff,

-against-

KATHLEEN SEBELIUS, Secretary
of Health and Human Services,

Defendant.
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ORDER ADOPTING REPORT
AND RECOMMENDATION
06-CV-2226 (DLI) (SMG)

DORA L. IRIZARRY, United States District Judge:

This case arises from the denial of plaintiff Diapulse Corporation of America's claims for Supplementary Medical Insurance Benefits under Part B of the Medicare Act, Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.* Plaintiff is a provider of the Diapulse medical device and an assignee of patients' claim for Medicare benefits. Plaintiff was denied Medicare reimbursement for 188 claims related to its device, which emits pulsed, high-frequency electromagnetic energy for the treatment of wounds and other medical conditions. Plaintiff's request for judicial review of defendant's final administrative decision denying its request for reimbursement was referred to the Honorable Steven M. Gold, United States Magistrate Judge on November 18, 2008.

On January 1, 2010, Judge Gold filed a Report and Recommendation ("R & R") recommending that plaintiff's motion for judgment on the pleadings be denied, and that defendant's motion for judgment on the pleadings be granted, except that a remand be issued with respect to the question of whether plaintiff is entitled to reimbursement pursuant to 42 U.S.C. § 1395pp for certain rental fees. On February 8, 2010, plaintiff filed objections to the R & R ("Pl.'s Obj."), and, on February 22, 2010, defendant filed a memorandum in support of the

R & R and in opposition to plaintiff's objections ("Def.'s Resp."). After carefully reviewing the R & R and related submissions, the magistrate judge's recommendations are adopted in their entirety.

In reviewing a magistrate judge's R & R, a district court "may accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge." 28 U.S.C. § 636(b)(1)(C). Where a party objects to an R & R, the court must engage in *de novo* review of those portions of the report to which the party specifically objects. *See United States v. Male Juvenile*, 121 F.3d 34, 38 (2d Cir. 1997). The court adopts the factual findings in the R&R, familiarity with which is assumed for purposes of this order.

The Second Circuit has held that referring the court to previously filed papers or arguments, without more, is a procedural default. *Mario v. P & C Food Markets, Inc.*, 313 F.3d 758, 767 (2d Cir. 2002) ("merely referring the court to previously filed papers or arguments does not constitute an adequate objection under. . . Fed. R. Civ. P. 72(b)"); *Schoolfield v. Department of Corrections*, 91-Civ-1691, 1994 WL 119740 *2 (S.D.N.Y., April 6, 1994) (finding that restating the relief sought in the motion and the facts upon which the party grounds the complaint is not a proper objection to a report and recommendation).

Here, with respect to the three decisions issued by Administrative Law Judge ("ALJ") Robert S. Habermann denying Medicare reimbursement for 135 claims, plaintiff argues that the magistrate judge erred by finding that Diapulse had the burden of establishing the safety and effectiveness of its equipment, and in failing to apply the "treating physician rule" to the Medicare coverage decisions. It further objects to ALJ Habermann's reliance on expert testimony from CIGNA Medical Director Dr. Robert D. Hoover. Plaintiff also contends that ALJ Habermann's decisions violated legal standards by according improper weight to Dr. Hoover's testimony, and improperly assessing plaintiff's studies, evidence of generally accepted standards in the medical community, and prior precedents. These objections are merely a reiteration of the arguments raised in the motion briefs.

Indeed, even a cursory review of the table of contents of plaintiff's objections to the R & R reveals that it is virtually identical to that of its memorandum of law in opposition to defendant's motion for judgment on the pleadings and in support of plaintiff's motion for judgment on the pleading. Accordingly, any objections to the recommendations concerning these arguments are deemed waived. Finding no clear error in these portions of the R & R, the court adopts them in their entirety.

As to the three decisions issued by ALJ David Z. Nisnewitz denying 53 claims submitted by Diapulse, plaintiff objects that the ALJ misconstrued the applicable national coverage determinations ("NCD"). He claims that the ALJ erred by applying the NCD's ban on home use when used to treat conditions other than open wounds, and imposing the NCD's limitations on the unsupervised use of electrical stimulation to electromagnetic therapy. Plaintiff also objects to the application of an NCD effective April 1, 2003 barring coverage for electromagnetic wound therapy to claims stemming from Diapulse rentals that began before the NCD's effective date. Plaintiff further objects that the magistrate judge erred by upholding the ALJ's refusal to consider prior ALJ decisions. The court is unpersuaded by plaintiff's objections, which are, again, mere reiterations of the arguments raised in the briefing and addressed by the magistrate judge in the R & R. Any other objections are deemed waived. Therefore, finding no clear error in the recommendations concerning these arguments, the court adopts them in their entirety as well.

Plaintiff also raises two specific objections to the R & R, neither of which has merit. First, plaintiff contends that the Administrative Procedure Act ("APA") rendered Dr. Hoover ineligible to testify as a neutral expert. It relies on 5 U.S.C. § 554(d), which precludes "[a]n employee or agent engaged in the performance of investigative or prosecuting functions for an agency in a case . . . [from] participat[ing] or advis[ing] in the decision" in that or a factually related case, "except as witness or counsel in public proceedings." This provision "prohibits agency staff from combining

prosecutorial and adjudicative functions in the same case.” *Blinder, Robinson & Co. v. S.E.C.*, 837 F.2d 1099, 1104 (9th Cir. 1988); *see also Donovan v. A. Amorello & Sons, Inc.*, 761 F.2d 61 (1st Cir. 1985) (noting that § 554(d) provides for separation of adjudicative and prosecutorial personnel in administrative agencies). Even assuming that Dr. Hoover can be deemed a Medicare employee or agent subject to the strictures of Section 554(d), that provision explicitly allows agents to participate in the case in issue as a “witness . . . in public proceedings” such as those at bar. Moreover, for the reasons detailed in the R & R, the court finds that the ALJ’s reliance on Dr. Hoover did not result in a conflation of Medicare’s adjudicative and prosecutorial functions. (*See* R & R at 15-18.) Although Dr. Hoover initially rejected plaintiff’s claim for rental of the Diapulse device in his capacity as a durable medical equipment carrier regional Medical Director, plaintiff took full advantage of the opportunity to present its own medical expert testimony, cross-examine Dr. Hoover, and offer rebuttal evidence. (*Id.* at 16.) Dr. Hoover reviewed plaintiff’s evidence with an open mind, and the ALJ clearly conducted a thorough, independent review of all the medical evidence, including Dr. Hoover’s opinion, before making a final coverage determination. (*Id.* at 17.) Accordingly, the ALJ did not violate Section 544(d) by relying on Dr. Hoover’s medical expert testimony.

Second, plaintiff complains specifically that the magistrate judge failed to address its argument that the ALJ’s construction of the Medicare Claims Processing Manual (“MCPM”), Chapter 32, Section 10.2, was flawed as applied to conditions other than open wounds. The MCPM states, in relevant part:

Medicare will not cover the device used for electromagnetic therapy for the treatment of wounds. However, Medicare will cover the service. Unsupervised home use of electromagnetic therapy will not be covered.

Plaintiff contends that the MCPM’s bar on coverage for home use of electromagnetic therapy devices is applicable only to wounds. However, plaintiff concedes that, under its reading of MCPM, coverage decisions for conditions such as swelling and edema would be left to the “reasonable

discretion of the DMERCs.” (Pl.’s Obj. at 20.)¹ The court sees no reason to disturb the magistrate judge’s finding that “it was reasonable for ALJ Nisnewitz to reject the idea of providing more generous coverage for Diapulse equipment” when used on conditions other than open wounds, based on his review of the evidence concerning the efficacy of such treatment. (R & R at 26.) Such finding was supported by substantial and “less compelling” evidence regarding the benefits of Diapulse therapy as compared to similar treatment in cases involving wounds. (*Id.*)

Finally, with respect the magistrate judge’s recommendation of remand, plaintiff requests a directive that the ALJ allow plaintiff to respond to any evidence purportedly showing that plaintiff had reason to know that coverage would be denied. Even where Medicare benefits have been determined not to be reasonable or necessary, an assignee may be entitled to reimbursement if it did not know, and did not have reason to know that coverage would be denied. (*See* R & R. at 26-27.) The case is remanded for the limited purpose of allowing the ALJ to supplement his written decision as to plaintiff’s right to recovery under 42 U.S.C. § 1395pp(a) and 20 C.F.R. § 411.406, and clarify the basis for his finding that plaintiff had notice that Diapulse treatment would not be covered for ailments such as pain swelling and edema. If the ALJ cannot explain his decision based on the evidence adduced in the existing record, further fact-finding proceedings in which both parties can proffer additional evidence are to be conducted. Plaintiff’s request to present additional evidence is granted to this extent.

Wherefore, upon due consideration, the court adopts Judge Gold’s exceptionally thorough and well-reasoned R & R in its entirety and denies plaintiff’s motion for judgment on the pleadings for the reasons set forth therein. Defendant’s motion for judgment on the pleadings is granted in part and denied to the extent that the case is remanded to enable the ALJ to

¹ This is also true with respect to plaintiff’s objection that NCD 280.1’s bar on coverage for home use of electrical stimulation should not be extended to electromagnetic therapy—coverage decisions would be left to the DMERC’s discretion.

supplement his decision and clarify the basis for his conclusion as to plaintiff's right to reimbursement pursuant to 42 U.S.C. § 1395pp and 20 C.F.R. § 411.406. If the ALJ cannot explain his decision based on the evidence adduced in the existing record, further fact-finding proceedings in which both parties can proffer additional evidence are to be conducted.

SO ORDERED

DATED: Brooklyn, New York
March 17, 2010

/s/
DORA L. IRIZARRY
United States District Judge